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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/179,188

10/27/1998

TOSHINARI SAKURAI

KAS-125

5396

24956

7590

06/21/2005

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/179,188

**Applicant(s)**

SAKURAI ET AL.

**Examiner**

David M. Naff

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,21,24,29,33-36,53-59 and 65-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21,24,29 and 33-36 is/are allowed.
- 6) ☒ Claim(s) 53-59 and 65-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

An amendment of 4/13/05 in response to an office action of 10/14/04, amended claims 53 and 56, canceled claims 60-64, and added new claims 65-72.

Claims examined on the merits are 20, 21, 24, 29, 33, 33-36, 53-59, and 65-72, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 53-59 and 65-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to disclose methods as now claimed by claims 53-59 and 65-72. The specification discloses only an invention of purifying nucleic acids by a method requiring steps as in claim 20. Description is not found in the specification of a method for purification of nucleic acids as required by claims 53 and 65 that omits steps of mixing, contacting and isolating prior to washing as required by lines 4-12 of claim 20. Additionally, support is not found in the specification for washing a solid phase that does not contain bound nucleic acids as encompassed by lines 9-11 of claims 53 and 65, and for modifying the mixing step of claim 53 as required by

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claim 56. Furthermore, support is not found in the specification for steps in claim 65 of mixing together as in lines 3-5 where a solid phase is present, and then contacting with a solid phase as required in lines 6-8. Methods having steps as required by claims 53-59 and 65-72 are not found in the specification when originally filed.

***Claim Rejections - 35 USC § 112***

Claims 53-59 and 65-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is unclear as to the form of the solid phase when washed in lines 9-11 since mixing as in lines 6-8 results in a mixture rather than merely a solid phase. Is the solid phase in the mixture when washed, or is it in some other form? Requiring eluting nucleic acids bound to the solid phase as in the last two lines of claim 53 is confusing since a previous step of binding nucleic acids to the solid phase has not been required.

Claim 56 is unclear by not further limiting mixing as in lines 6-8 of claim 53, but requiring a different mixing procedure that is not within the scope of mixing together as in lines 6-8 of claim 53. Additionally, there is not clear antecedent basis for "the mixing step" in line 2 of claim 56 since claim 53 does not recite "mixing step".

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Claims 53 and 65 (line 9) are unclear as to whether the solid phase washed contains bound nucleic acids since the solid phase in line 9 is not required to contain bound nucleic acids.

Claim 65 is confusing by requiring (lines 6-8) contacting the mixture obtained from the mixing step with a solid phase since a solid phase is previously required when mixing together in lines 3-5. Is the solid phase in lines 6-8 in addition to that in lines 3-5? How can a solid phase be contacted with the mixture from a mixing step when the mixing step involves mixing with a solid phase to produce a mixture containing a solid phase? Additionally, there is not clear antecedent basis for "the mixing step" in line 6 since "mixing step" is not previously recited.

#### **Conclusion**

Claims 20, 21, 24, 29 and 33-36 are allowed.

Claims 53-59 and 65-72 are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

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is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651